

Restriction is only proper if the claims of the restricted groups are either independent or patentably distinct. The burden of proof is on the Office to provide reasons and/or examples to support any conclusion with regard to patentable distinctness. M.P.E.P. § 803.

Applicants respectfully traverse the requirement for restriction on the grounds that the Office has not provided adequate reasons and/or examples to support a conclusion of patentable distinctness between the identified groups.

The Office, citing PCT Rule 13.1 and 13.2, contend that Groups I-V do not relate to a single general inventive concept because they lack the same or corresponding special technical features (outstanding Official Action at page 2, last paragraph). However, Applicants traverse the requirement for restriction on the grounds that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. The Authority did not take the position that unity of invention was lacking in the International Application, and examined all the claims together (see the International Preliminary Examination Report appended herewith). Applicants note that PCT Article 27(1) states that no national law shall require compliance with requirements relating to the form and contents of the International Application which are “different from or in addition to” those provided in the Patent Cooperation Treaty and the Regulations. In fact, Applicants point to section V of the International Preliminary Examination Report, in which the International Authority found the present application to possess novelty, as well as an inventive step.

The Office states that “Hoshino et al (from PTO-892) teach a sorbitol dehydrogenase that can be construed as a polypeptide comprising an amino acid sequence of SEQ ID NO:1 wherein one or more amino acid residues have been deleted, substituted, inserted, added or modified.” Furthermore, at page 3 of the outstanding Official Action, the Office alleges that the special technical features of Groups I-V are different, and thereby concludes that they are

“not so linked by the same or a corresponding special technical feature.” However, Applicants note that the Office has simply stated a conclusion, and has not supplied reasons or examples in support of this conclusion. Such reasons and examples are particularly important, since, as discussed above, they contradict the International Preliminary Examination Report, which found no “lack of unity of invention.” Accordingly, Applicants respectfully submit that the requirement for restriction is improper, and it should be withdrawn.

The Office also states that under 35 U.S.C. §37 C.F.R. § 1.475(d), “a national stage may not relate to multiple products or multiple processes in one application.” Applicants have reviewed 37 C.F.R. § 1.475(d) and respectfully submit that 37 C.F.R. § 1.475(d) does not prohibit multiple products or processes in one application, as asserted by the Office. Rather, it simply states that if multiple products and processes are claimed, “the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims.” Accordingly, Applicants respectfully submit that the requirement for restriction is improper, and it should be withdrawn.

Finally, the M.P.E.P. § 803 states as follows:

If the search and examination of an entire application can be made without a serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Applicants respectfully submit that a search of all the claims would not impose a serious burden on the Office, particularly since the International Searching Authority has searched all of the claims together.

Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants respectfully request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

Respectfully submitted,

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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 09348	<b>FOR FURTHER ACTION</b> <span style="float: right;">See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)</span>	
International application No. PCT/JP00/01608	International filing date (day/month/year) 16 March 2000 (16.03.00)	Priority date (day/month/year) 17 March 1999 (17.03.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/53, 9/04, 1/21, C12P 19/02, 7/60		
Applicant FUJISAWA PHARMACEUTICAL CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 04 September 2000 (04.09.00)	Date of completion of this report 16 October 2000 (16.10.2000)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01608

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:

pages \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the claims:

pages \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, as amended (together with any statement under Article 19)

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the drawings:

pages \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the sequence listing part of the description:

pages \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages \_\_\_\_\_ the claims, Nos. \_\_\_\_\_ the drawings, sheets/fig. \_\_\_\_\_5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01608

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step (IS)	Claims	1-22	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

**2. Citations and explanations**

Document 1: KR, 98069057, A (Korea Adv. Inst. Sci. & Technology), 26 October, 1998 (26.10.98)

Document 2: Effect of toluene-permeabilization on oxidation of D-sorbitol to L-sorbose by *Gluconobacter suboxydans* cells immobilized in calcium alginate, (Young-Min Park et al.), Biotechnology Letters, 1994, Vol. 16, No. 4, pages 345-348

The subject matter of claims 1-22 is not disclosed in either of documents 1 or 2 cited in the ISR, and is thus considered to be novel.

The enzyme having the physico-chemical properties disclosed in claim 1, the amino acid sequence represented by sequence no. 1, and the DNA represented by sequence no. 2, are not disclosed in either of the above-mentioned documents.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01608

## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO,99/20763,A1	29 April 1999 (29.04.1999)	13 October 1998 (13.10.1998)	17 October 1997 (17.10.1997)
[E,Y]			
EP,955358,A	10 November 1999 (10.11.1999)	08 March 1999 (08.03.1999)	13 March 1998 (13.03.1998)
[E,XY]			

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
		